

REMARKS

I. Amendments to the Claims

Claim 1 has been amended to specify a cell concentration in the sample of “between about 10^5 to about 10^{10} cells/mL,” and further amended to specify that the sample is provided to either the “first or second” sample chamber. These amendments are believed to be supported in the present specification at page 5, lines 27-29 and page 9, lines 23-24, respectively.

Claims 4, 5, and 25 have been amended to improve the clarity of the claim language.

Claim 29 has been canceled.

Claim 30 has been amended to recite the concentration units of the sample. This amendment is believed supported at page 5, lines 27-29.

No new matter is believed to have been added. Claims 1-28 and 30 are active.

II. Replacement Drawings

Corrected Drawings (Figures 1 and 2) are provided herewith in the attached “Replacement Sheet.”

III. Rejection Under 35 U.S.C. 112

The Examiner has rejected claims 29 and 30 as indefinite. As noted above, claim 29 has been canceled, and thus the rejection in regard to claim 29 has been rendered moot.

Claim 30 has been amended, as suggested by the Examiner, to recite units of “cells/mL”.

Claim 1 has been amended, as suggested by the Examiner, to recite a cell concentration of “between about 10^5 to about 10^{10} cells/mL.” Claim 1 has been further amended to clarify that the sample is provided to the “first or second sample chamber”. Thus, the added sample cell concentration limitation clearly refers to the initial concentration of the sample upon “providing” it to the sample chamber. The sample itself is clearly added to either the first sample chamber, or in the alternative, the second sample chamber.

Applicants respectfully submit that the amended claims are definite, and request that the rejection be withdrawn.

IV. Rejection Under 35 U.S.C. 102(e) Over *Conlan*

The Examiner has rejected the claims as anticipated by US 2003/0029725 (*Conlan*), stating in part that “CONLAN teaches a method for the separation of molecules” in which “[a]pplying an electric potential between the electrodes [0053] causing movement of one micromolecule from one sample to another sample chamber across the membrane [0073]”¹ (underline added); that “CONLAN teaches that in use, an applied electric potential across the membrane allows migration of at least one of the micromolecules”² (underline added); and that “CONLAN teaches that movement of the micromolecules across the membrane occurs upon application of the electric potential [0073]”³ (underline added). Thus, the Examiner has stated on the record that *Conlan* teaches a method for separating molecules, wherein these “micromolecules” migrate across a membrane as a result of the application of electric potential.

However, the process of the claimed invention comprises a step (b) in which application of an electric potential causes “at least one cell type in the first sample chamber or the second sample chamber to move through the first ion-permeable barrier” (underline added). Thus, the claimed process is a method of separating cells, whereas the Examiner has expressly stated that *Conlan* teaches a method of separating “micromolecules” (i.e., “molecules deemed to be less than about 5 kDa”⁴). Cells are manifestly quite different from “micromolecules”, and thus the claimed process is quite different from the process of *Conlan*. Accordingly, Applicants request that the rejection be withdrawn.

The Examiner also points to paragraph [0090] of *Conlan*, which states that sample can include “microbial cultures.” Applicants note, however, that *Conlan* does not indicate whether such microbial cultures contain a mixture of cell types, as required by the claimed invention, and

¹ Office Action, page 4, first paragraph.

² Office Action, page 5, lines 9-11.

³ Office Action, page 5, lines 15-17.

⁴ *Conlan*, paragraph [0099].

does not indicate whether the method disclosed in *Conlan* causes one type of cell to be separated from others, as required by the claimed process. For example, a microbial culture could contain a single type of microbial cell (rather than the “mixture of cell types” required by the claimed invention). Furthermore, even if the microbial culture contained a mixture of cell types, what is separated from such sample need not be cells, but could reasonably be “micromolecules”. Indeed, *Conlan* only teaches the separation of “micromolecules” from samples (rather than the separation of “a cell type” from sample), and thus even from a mixture of microbial cells, *Conlan* reasonably only teaches the separation of “micromolecules.” Thus paragraph [0090] of *Conlan* does not reasonably disclose or suggest the claimed process of “separating a cell type from a mixture of cell types.”

The Examiner also notes that paragraph [0079] of *Conlan* discloses separation membranes having a molecular weight cut off of “1000 kDa.”⁵ Applicants note that membranes having molecular weight cut off values in this range would have pores that are far too small to permit the passage of microbial cells. For example, commercial membranes having a molecular weight cut off (“MWCO”) of “1000 K” (i.e., kDa) have a nominal pore size of only about 100 nm (0.1 μ m)⁶, whereas bacterial cells are known to have dimensions in the range of a few microns.⁷ Thus, the largest membrane pore sizes taught by *Conlan* are about 10 times smaller than the typical dimensions of bacterial cells. Reasonably, then, the separation membranes taught by *Conlan* would be incapable of effecting the claimed process for separating a cell type from a mixture of cell types. Accordingly, *Conlan* fails to teach or suggest the claimed invention. Applicants request that the rejection be withdrawn.

With regard to claims 18 and 19, the Examiner points to *Conlan*’s disclosure of the recovery of an azorubine-containing sample. Pending claims 18 and 19 recite a “cell type” of which, after separation, 50% or 60% “remains viable or substantially unchanged.” However, Applicants note that azorubine is a synthetic food dye⁸ and is therefore not a “cell type”. Thus, *Conlan* clearly does not disclose cells which remain “substantially unchanged” after a separation process.

⁵ Office Action, page 6, 3rd paragraph.

⁶ See, e.g., Pall Laboratory Selection Guide, http://www.pall.com/laboratory_7046.asp.

Accordingly, *Conlan* clearly fails to teach the claimed invention. Applicants therefore request that the rejection be withdrawn.

V. Rejection Under 35 U.S.C. 103 Over *Conlan*, or *Conlan* and *Wu*

The Examiner has rejected various claims as obvious over *Conlan*, or the combination of *Conlan* and *Wu* (US 6,824,995).

A. Rejection over *Conlan*

As discussed above, *Conlan* fails to disclose various limitations of the claimed process. Specifically, (1) *Conlan* never discloses separating a cell type from a mixture of cells, (2) *Conlan* fails to disclose a mixture of cells, and (3) *Conlan* teaches preferred separation membrane pore sizes which are far too small to reasonably allow the separation of microbial cells. Thus, *Conlan* fails to support *prima facie* obviousness.

Furthermore, (and as stated on the record by the Examiner), *Conlan* teaches methods of separating “micromolecules” from samples. If *Conlan* was modified to provide a process for separating a cell type from a mixture of cell types, Applicants submit that the modified process would no longer be suitable for the purpose intended by *Conlan*, as the larger membrane pore sizes necessary to effect the separation of cells would reasonably be nonselective for the much small “micromolecules” separated by *Conlan*. Thus, as a matter of law, modifying *Conlan* in this manner would not be obvious. See M.P.E.P. 2143.01 (V) (“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)”).

Accordingly, for the reasons stated above, Applicants request that the rejection be withdrawn

⁷ See, e.g., “Bacteria”, <http://en.wikipedia.org/wiki/Bacteria>

⁸ Azorubine, <http://en.wikipedia.org/wiki/Azorubine>.

B. Rejection over *Conlan* and *Wu*

As discussed above, *Conlan* fails to disclose separating a cell type from a mixture of different cell types, and indeed fails to even disclose mixtures of cell types. *Wu* fails to correct these deficiencies. *Wu* simply discloses a method of determining the metastatic ability of cancer cells, apparently to allow the correlation of various genetic factors to metastatic ability. *Wu* states that this test is used to quantify “the rate of invasiveness of a given cell line”⁹ (underline added). In other words, *Wu* only measures the motility of one type of cell at a time, and thus does not teach using such membranes to separate one type of cell from a mixture of cell types as required by the claimed process. Thus neither *Conlan* nor *Wu* disclose separating one type of cell from a mixture of cells. Accordingly, the combination of *Conlan* and *Wu* necessarily fails to teach or suggest the claimed process.

Applicants further note that *Wu*’s use of membranes discussed above is not part of an electrophoretic separation process, and no electric potential is applied. Indeed, *Wu*’s only mentions gel electrophoresis of various cellular extracts, rather than the claimed membrane-based electrophoresis process.¹⁰ Thus, *Wu* clearly does not disclose “causing at least one cell type” to move through a membrane by applying an “electric potential” as required by step (b) of the claimed process.

As noted above, *Conlan* does not disclose separating a cell type by electrophoresis. Since *Wu* also does not disclose an electrophoretic separation of cells, the combination of *Conlan* and *Wu* necessarily fails to disclose the claimed process. Accordingly, the combination of *Conlan* and *Wu* necessarily fails to teach or suggest the claimed process.

CONCLUSION

In view of the foregoing, Applicant respectfully submits that no further impediments exist to the allowance of this application and, therefore, requests an indication of allowability. However, the Examiner is requested to call the undersigned if any questions or comments arise.

⁹ *Wu*, col. 18, lines 11-12.

¹⁰ *E.g.*, *Wu*, col. 3, line 26-41; col. 18, lines 57-67.

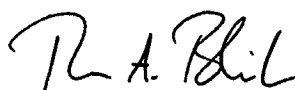
The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

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